

PCT/IB02/04690
LEK PHARMACEUTICALS d.d.
L15-17106.2
August 2, 2004

New Claims

1. A stable pharmaceutical composition of erythropoietin (EPO), which consists of:
 - a. a therapeutically effective amount of EPO
 - b. a pharmaceutically acceptable pH buffering system, and
 - c. polyvinylpyrrolidone (PVP) and optionally
- a poloxamer as an additional stabiliser,
 - d. an isotonicifying agent and/or
 - e. one or more pharmaceutically acceptable excipient(s) selected from the group consisting of polyols, hydroxypropylcellulose, methylcellulose, macrogol esters and ethers, glycol and glycerol esters, and amino acids.
2. The composition according to claim 1, which is free of additives derived from human and/or animal origin.
3. The composition of claim 1 or 2, wherein the composition is aqueous.
4. The composition of any one of claims 1 to 3, wherein the pharmaceutical quantity of EPO is formulated to provide a quantity per dose in the range of about 500 to about 100000 IU EPO.
5. The composition of claim 4, wherein the pharmaceutical quantity is formulated to provide a quantity per dose selected from the group consisting of about 1000 IU, about 2000IU, about 3000 IU, about 4000 IU, about 10000 IU, about 20000 IU, about 25000 IU and about 40000 IU.
6. The composition of any one of claims 1 to 5, wherein the pH buffering system provides a pH range from about 6 to about 8.

7. The composition of claim 6, wherein the pH buffering system provides a pH range from about 6.8 to about 7.5.
8. The composition of claim 6, wherein the pH buffering system provides a pH of about 7.0.
9. The composition of any one of claims 1 to 8, wherein the pH buffering system is phosphate buffer.
10. The composition of any one of claims 1 to 9, wherein PVP is comprised in a range of about 0.01% to about 1%.
11. The composition of claim 10, wherein PVP is comprised in a range of about 0.1% to about 1%.
12. The composition of claim 10, wherein the concentration of PVP is about 0.5%.
13. The composition of any one of claims 1 to 12, wherein said PVP has a K value in a range from K12 to K18.
14. The composition of any one of claims 1 to 13, wherein said isotonicifying agent is selected from the group consisting of inorganic salts.
15. The composition of claim 14, wherein said isotonicifying agent is NaCl.
16. The use of PVP as the sole stabiliser for the stabilisation of erythropoietin (EPO) in an aqueous solution.
17. A process for preparing a composition containing erythropoietin (EPO), comprising mixing EPO with PVP, wherein the composition of any of claims of 1 to 16 is prepared.
18. Use of a composition of any one of claims 1 to 15 for the preparation of a medicament for the treatment and/or prevention of diseases indicated for erythropoietin (EPO).